

Docket No. 0575/79180-B/JPW/CSS

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Thomas M. Jessell et al.
Serial No. : 10/789,308
Filed : February 26, 2004
For : SYSTEMS AND METHODS FOR SCREENING FOR
MODULATORS OF NEURAL DIFFERENTIATION

30 Rockefeller Plaza
New York, New York 10112
June 30, 2009

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
AS A SUBMISSION UNDER 37 C.F.R. §1.114 ACCOMPANYING
REQUEST FOR CONTINUED EXAMINATION

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following references, which are listed on Form PTO-1449 (**Exhibit A**).

Reference items 1-8 are either U.S. Patents or U.S. Patent Application Publications. Pursuant to 37 C.F.R. §1.98(a)(2), copies of references 1-8 are not being submitted.

Copies of the documents listed herein as items 9-69 are attached hereto as **Exhibits 1-61**.

1. U.S. Patent No. 5,753,506, issued May 19, 1998 to Johe;

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2. U.S. Patent No. 6,432,711, issued August 13, 2002 to Dinsmore et al.;
3. U.S. Patent No. 6,646,113, issued November 11, 2003 to Dreyfuss et al.;
4. U.S. Patent No. 7,250,294, issued July 31, 2007 to Carpenter et al.;
5. U.S. Patent No. 7,390,659, issued June 24, 2008 to Jessell et al.;
6. U.S. Patent Application Publication No. 2004-0224302, published November 11, 2004 (Jessell et al.);
7. U.S. Patent Application Publication No. 2007-0185024, published August 9, 2007 (Jessell et al.);
8. U.S. Patent Application Publication No. 2007-0224650, published September 27, 2007 (Jessell et al.);
9. PCT International Application Publication No. WO2001/174344, published October 11, 2001 (Baxter et al.) **(EXHIBIT 1)**;
10. PCT International Application Publication No. WO2004/007665, published January 22, 2004 (Jessell et al.) **(EXHIBIT 2)**;

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11. PCT International Application Publication No. WO2005/081857, published September 9, 2005 (Jessell et al.) (**EXHIBIT 3**);
12. PCT International Application Publication No. WO2005/082002, published September 9, 2005 (Jessell et al.) (**EXHIBIT 4**);
13. Arnold et al., "Construction of a Plasmid Containing Human SMN, the SMA Determining Gene, Coupled to EGFP." *Plasmid*, 47(2): 79-87, 2002 (**EXHIBIT 5**);
14. Bjorklund et al., "Embryonic stem cells develop into functional dopaminergic neurons after transplantation in a Parkinson rat model." *Proc Natl Acad Sci USA*, 99: 2344-2349, 2002 (**EXHIBIT 6**);
15. Briscoe et al., "Homeobox gene Nkx2.2 and specification of neuronal identity by graded Sonic hedgehog signaling." *Nature*, 398: 622-627, 1999 (**EXHIBIT 7**);
16. Chung et al., "Deubiquitinating enzymes: their diversity and emerging roles." *Biochem Biophys Res Commun.*, 266:633-640, 1999 (**EXHIBIT 8**);
17. Clontech, "New Living ColorsTM GFP Mammalian Vectors", CLONTECHniques, July 1996 (**EXHIBIT 9**);
18. Corse et al., "Preclinical Testing of Neuroprotective Neurotrophic Factors in a Model of Chronic Motor Neuron

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Degeneration." *Neurobiology of Disease*, 58(7): 335-346, July 1999 (**EXHIBIT 10**);

19. Derby et al., "GDNF is trophic for mouse motoneurons that express a mutant superoxide dismutase (SOD-1) gene." *ALS and Other Motor Neuron Disorders*, 1(2): 113-122, March 2000 (**EXHIBIT 11**);
20. Fraichard et al., "In vitro differentiation of embryonic stem cells into glial cells and functional neurons." *J. Cell Sci.*, 108: 3181-3188, 1995 (**EXHIBIT 12**);
21. Geisert et al., "The neuronal response to injury as visualized by immunostaining of class III beta-tubulin in the rat." *Neurosci Lett.*, 102: 137-141, 1989 (**EXHIBIT 13**);
22. Ghosh et al., "Distinct roles for bFGF and NT-3 in the regulation of cortical neurogenesis." *Neuron*, 15(1): 89-103, 1995 (**EXHIBIT 14**);
23. Goueli et al., "A novel and simple method to assay the activity of individual protein kinase in crude tissue extracts." *Anal Biochem*, 225(10):10-17, 1995 (**EXHIBIT 15**);
24. Hsieh-Li et al., "A mouse model for spinal muscular atrophy." *Nat Genet.*, 24: 66-70, 2000 (**EXHIBIT 16**);

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25. Hynes et al., "Specification of dopaminergic and serotonergic neurons in the vertebrate CNS." Review. *Curr. Opin. Neurobiol.*, 9: 26-36, 1999 (**EXHIBIT 17**);
26. Lee and Jessell, "The specification of dorsal cell fates in the vertebrate central nervous system." *Annu. Rev. Neurosci.* 22: 261-294, 1999 (**EXHIBIT 18**);
27. Jessell et al., "The decade of the developing brain." *Curr. Opin. Neurobiol.*, 10: 599-611, 2001 (**EXHIBIT 19**);
28. Kawasaki et al., "Induction of midbrain dopaminergic neurons from ES cells by stromal cell-derived inducing activity." *Neuron*, 28: 31-40, 2000 (**EXHIBIT 20**);
29. Lee et al., BIOSIS Accession No. 2004:197764, Abstract from the Meeting of the Society for Neuroscience, November 8-12, 2003 (**EXHIBIT 21**);
30. Lee et al., BIOSIS Accession No. 200400198323, "Motoneuronal differentiation of human ES cells." Abstract from the Meeting of the Society for Neuroscience, November 8-12, 2003 (**EXHIBIT 22**);
31. Li et al., "Generation of purified neuronal precursors from embryonic stem cells by lineage selection." *Curr Biol.*, 8:971-974, 1998 (**EXHIBIT 23**);
32. Marquardt et al., "Cracking the transcriptional code for cell specification in the neural tube." *Cell*, 106: 651-654, 2001 (**EXHIBIT 24**);

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33. Mettling et al., "Survival of newly postmitotic motoneurons is independent of exogenous trophic support." *J. Neurosci.*, 15(4):3128-3137, 1995 (**EXHIBIT 25**);
34. Monani et al., "Animal models of spinal muscular atrophy." *Review. Hum Mol Genet.*, 9(16): 2451-2457, 2000 (**EXHIBIT 26**);
35. Muhr et al., "Assignment of early caudal identity to neural plate cells by a signal from caudal paraxial mesoderm." *Neuron*, 19: 487-502, 1997 (**EXHIBIT 27**);
36. Mullen et al., "NeuN, a neuronal specific nuclear protein in vertebrates." *Development*, 116: 201-211, 1992 (**EXHIBIT 28**);
37. Nagai et al., "Rats expressing human cytosolic copperzinc superoxide dismutase transgenes with amyotrophic lateral sclerosis: associated mutation develop motor neuron disease." *J. Neurosci.*, 21: 9246-9254, 2001 (**EXHIBIT 29**);
38. Nicholson et al., "Mice, the motor system, and human motor neuron pathology." *Review. Mamm Genome*, 11: 1041-1052, 2000 (**EXHIBIT 30**);
39. Pevny et al., "A role for SOX1 in neural determination." *Development*, 125: 1967-1978, 1998 (**EXHIBIT 31**);
40. Simeoni et al., "Motoneuronal cell death is not correlated with aggregate formation of androgen receptors

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containing an elongated polyglutamine tract." Human Molecular Genetics, 9(1): 133-144, 2000 (**EXHIBIT 32**);

41. Sockanathan et al., "Motor neuron-derived retinoid signalling specifies the subtype identity of spinal motor neurons." Cell, 94: 503-514, 1998 (**EXHIBIT 33**);
42. Spinella-Jaegle et al., "Sonic hedgehog increases the commitment of pluripotent mesenchymal cells into the osteoblastic lineage and abolishes adipocytic differentiation." J Cell Sci., 114: 2085-2094, 2001 (**EXHIBIT 34**);
43. Talbot et al., "Characterization of a gene encoding Survival Motor Neuron (SMN)-related protein, a constituent for the spliceosome complex." Human Molecular Genetics, 7(13): 2149-2156, 1998 (**EXHIBIT 35**);
44. Turgeon et al., "Prevention of Thrombin-Induced Motoneuron Degeneration with Different Neurotrophic Factors in Highly Enriched Cultures." J Neurobiol., 38(4): 571-580, 1999 (**EXHIBIT 36**);
45. Vallier et al., "An efficient system for conditional gene expression in embryonic stem cells and in their in vitro and in vivo differentiated derivatives." Proc Natl Acad Sci USA, 98(5): 2467-2472, 2001 (**EXHIBIT 37**);
46. Weinstein et al., "Neural induction." Annu Rev Cell Dev Biol., 15: 411-433. 1999 (**EXHIBIT 38**);

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47. Westmoreland et al., "Neuronal development of embryonic stem cells: a model of GABAergic neuron differentiation." Biochem Biophys Res Commun., 284: 674-680, 2001 (**EXHIBIT 39**);
48. Zhu et al., "Sonic hedgehog and BMP2 exert opposing actions on proliferation and differentiation of embryonic neural progenitor cells." Dev Biol., 215(1): 118-129, 1999 (**EXHIBIT 40**);
49. The American Heritage Dictionary of the English Language. 4th Ed. (2000). Term: "Motoneuron" (**EXHIBIT 41**);
50. Office Action issued by the United States Patent and Trademark Office on July 19, 2004 in connection with application No. 10/196,882 (**EXHIBIT 42**);
51. Office Action issued by the United States Patent and Trademark Office on October 1, 2004 in connection with Application No. 10/196,882 (**EXHIBIT 43**);
52. Office Action issued by the United States Patent and Trademark Office on May 3, 2005 in connection with Application No. 10/196,882 (**EXHIBIT 44**);
53. Office Action issued by the United States Patent and Trademark Office on February 22, 2006 in connection with Application No. 10/196,882 (**EXHIBIT 45**);

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54. Office Action issued by the United States Patent and Trademark Office on August 14, 2006 in connection with application No. 10/789,266 (**EXHIBIT 46**);
55. Final Office Action issued by the United States Patent and Trademark Office on October 27, 2006 in connection with Application No. 10/196,882 (**EXHIBIT 47**);
56. Office Action issued by the United States Patent and Trademark Office on April 30, 2007 in connection with Application No. 10/789,266 (**EXHIBIT 48**);
57. Office action issued by the United States Patent and Trademark Office on June 22, 2007 in connection with Application No. 10/196,882 (**EXHIBIT 49**);
58. Office Action issued by the United States Patent and Trademark Office on April 30, 2008 in connection with application No. 11/510,038 (**EXHIBIT 50**);
59. Office Action issued by the United States Patent and Trademark Office on May 9, 2008 in connection with application No. 11/510,366 (**EXHIBIT 51**);
60. Office Action issued by the United States Patent and Trademark Office on December 12, 2008 in connection with Application No. 11/510,038 (**EXHIBIT 52**);
61. Office Action issued by the United States Patent and Trademark Office on December 17, 2008 in connection with Application No. 11/510,366 (**EXHIBIT 53**);

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62. PCT International Preliminary Examination Report issued April 4, 2005, in connection with PCT/US2003/20399, filed June 26, 2003 (**EXHIBIT 54**);
63. PCT International Search Report issued October 7, 2004 in connection with PCT/US2003/20399, filed June 26, 2003 (**EXHIBIT 55**);
64. Written Opinion of International Searching Authority issued June 14, 2007 in connection with PCT/US2005/05166, filed February 18, 2005 (**EXHIBIT 56**);
65. PCT International Search Report issued June 14, 2007 in connection with PCT/US2005/05166, filed February 18, 2005 (**EXHIBIT 57**);
66. PCT International Preliminary Report on Patentability issued July 10, 2007 in connection with PCT/US2005/05166, filed February 18, 2005 (**EXHIBIT 58**);
67. Written Opinion of International Searching Authority issued June 26, 2007 in connection with PCT/US2005/005877, filed February 22, 2005 (**EXHIBIT 59**);
68. PCT International Search Report issued June 26, 2007 in connection with PCT/US2005/005877, filed February 22, 2005 (**EXHIBIT 60**); and
69. PCT International Preliminary Report on Patentability issued July 17, 2007 in connection with PCT/US2005/005877, filed February 22, 2005 (**EXHIBIT 61**).

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This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(b)(4). The Examiner is respectfully requested to make these references of record in the present application by initialing and returning a copy of the enclosed Form PTO-1449.

Summary

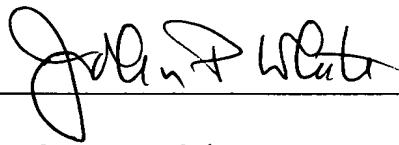
Applicants request that the Examiner review the references 1-69 and make them of record in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

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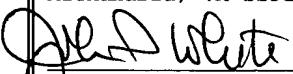
No fee, other than the enclosed fee of \$405.00 for filing a Request for Continued Examination, is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement and Request for Continued Examination. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
30 Rockefeller Plaza
New York, New York 10112
(212) 278-0400

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